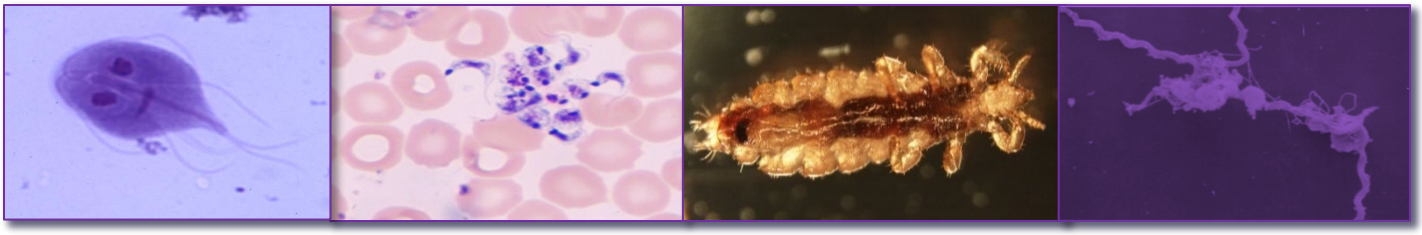
Annual Report
Bureau of Laboratories
Fiscal Year 2020

BUREAU OF LABORATORIES



The Bureau of Laboratories was established under provisions of the revised Public Health Code – Act 368 of 1978, Part 96 (3333.9601)

Our Vision:

The Bureau of Laboratories is a strong, more diverse team within an integrated public health system. We utilize advanced technology and innovative leadership to provide comprehensive public health services in our dynamic global community.

Our Mission:

The Bureau of Laboratories is dedicated to continued leadership in providing quality laboratory science for healthier people and communities through partnerships, communication, and technical innovation.

Sandip Shah, PhD., HCLD(ABB)
Laboratory Director

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INTRODUCTION

The Michigan Department of Health and Human Services Bureau of Laboratories was founded in 1907. The Bureau of Laboratories (BOL) provides laboratory support for local health departments, other state health departments, hospitals, and physicians throughout the State of Michigan. In addition, the BOL works closely with other states and federal agencies such as the Centers for Disease Control and Prevention (CDC) and the Federal Select Agent Program.

The **Division of Chemistry and Toxicology** provides expertise for testing clinical specimens for human exposures and environmental samples for contamination of chemical agents such as lead and mercury. This division is designated as a CDC Laboratory Response Network-Chemical (LRN-C) Level 1 laboratory that would test clinical samples in the event of a regional chemical exposure.

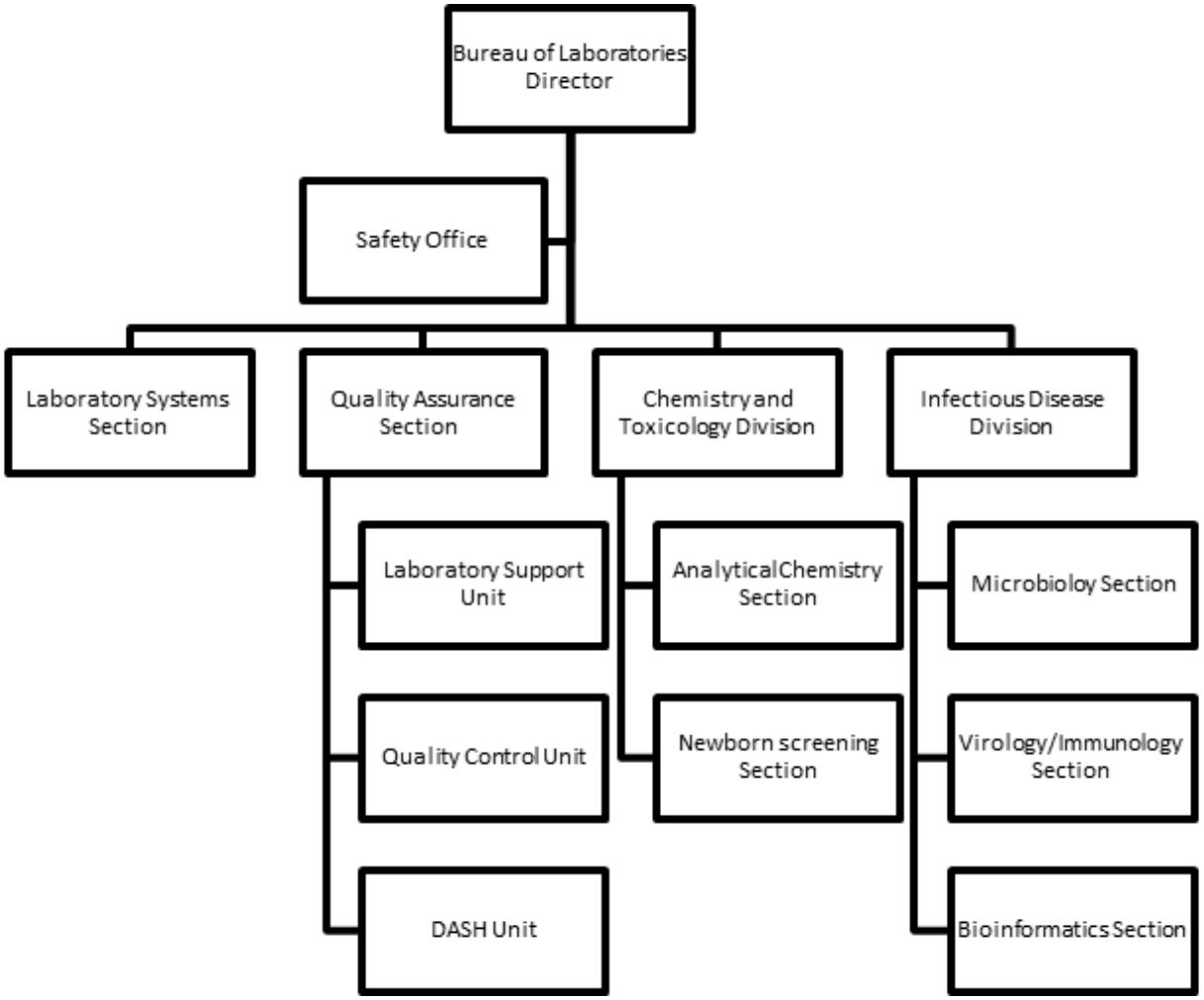
The Newborn Screening (NBS) section performs tests for every infant born in the State of Michigan that includes over 50 congenital and metabolic disorders, such as cystic fibrosis and sickle cell anemia. This laboratory testing program is part of a comprehensive state program for newborns including referral to specialty clinics and follow-up care to prevent and treat serious health problems.

The **Division of Infectious Disease** (DID) supports local, state, and national public health agencies. It provides quality reference and specialized testing services for rapid and effective detection and surveillance of emerging and existing communicable diseases such as SARS CoV-19, Jamestown Canyon virus, and Eastern Equine Encephalitis virus, along with foodborne illness and sexually transmitted infections. This division is designated as a CDC Laboratory Response Network-Biological (LRN-B) Tier 1 laboratory that tests biological samples for the CDC, the Federal Select Agent program, and the Food Emergency Response Network (FERN) for food safety.

The Health & Safety Office, Data and Specimen Handling unit, Quality Assurance Section, and the Laboratory Systems Section supports all areas of the laboratory. The Health & Safety Office provides several required annual employee training programs. The Data and Specimen Handling Unit receives all samples for laboratory testing, performs sample data entry, and is proficient in

Division 6.2 Packing and Shipping. The Laboratory System Section maintains the laboratory information management systems and the Laboratory Outreach section that develops and delivers LRN-C, LRN-B, and K-12 Explore Lab Science education and training programs throughout the State of Michigan.

The BOL Organizational Chart is outlined below.



ACCOMPLISHMENTS

In March 2020, Michigan identified the first case of SARS-CoV-2, which is a human infection caused by a coronavirus. The BOL had an extensive role in the public health response to this emerging pathogen in Michigan that became a worldwide pandemic know as COVID-19. The first human coronavirus detection test was developed by CDC and available for clinical laboratory use through an emergency use authorization (EUA) from the Food and Drug Administration (FDA).

- BOL was the first laboratory in Michigan to test for COVID-19. The BOL rapidly collaborated with and trained other laboratory partners to expand testing to other sites throughout the state. COVID-19 posed challenges to the public health system and caused some disruption to normal workflow at the BOL. The laboratory personnel rallied as a team to support scientists testing large volumes of clinical samples. Job duties changed for some laboratory personnel in order to rearrange the workload to accommodate scientists testing the enormous volumes of samples from persons suspected of exposure and focus on contraction of this coronavirus until more permanent solutions to maintain core laboratory capabilities could be implemented. As the COVID-19 pandemic progresses the BOL will continue to provide clinical laboratory training and healthcare partner support and offer testing and surveillance data to protect the health and welfare of Michigan residents.

- BOL was tasked with dissemination of federally funded clinical sample collection supplies for COVID-19 testing. From the start of the pandemic through the end of the 2020 fiscal year, the BOL warehouse personnel shipped over 10.2 million swabs and transport media kits to health agency partners involved with COVID-19 sample collection positioned throughout the State of Michigan.

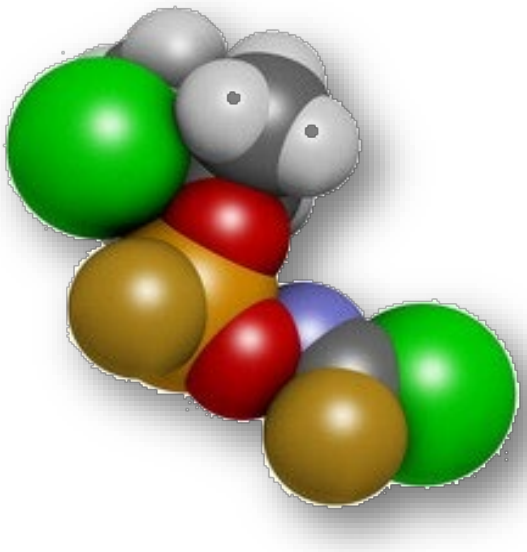
- The Laboratory System Section upgraded the respiratory virus panel test that included the addition of COVID-19 and enabled HL7 messaging for test data transfer to the CDC, all during a time when BOL electronic messaging increased 100-fold.

- Laboratory Information Systems employees (LIS) created ten COVID-19 Polymerase Chain Reaction (PCR) tests and one COVID-19 Sequencing test in the Laboratory Information Management System (LIMS) for use by the BOL and each of the seven Regional Laboratories. They also created two COVID-19 Antibody tests in LIMS for BOL.

- BOL employees actively represent the State of Michigan Public Health Laboratory in the national Association for Public Health Laboratories (APHL) committees and subcommittees, along with participating in speaking engagements, authorship of scientific articles, and poster presentation sessions during national conferences.

- BOL successfully completed 157 proficiency test events from 11 different proficiency test providers.

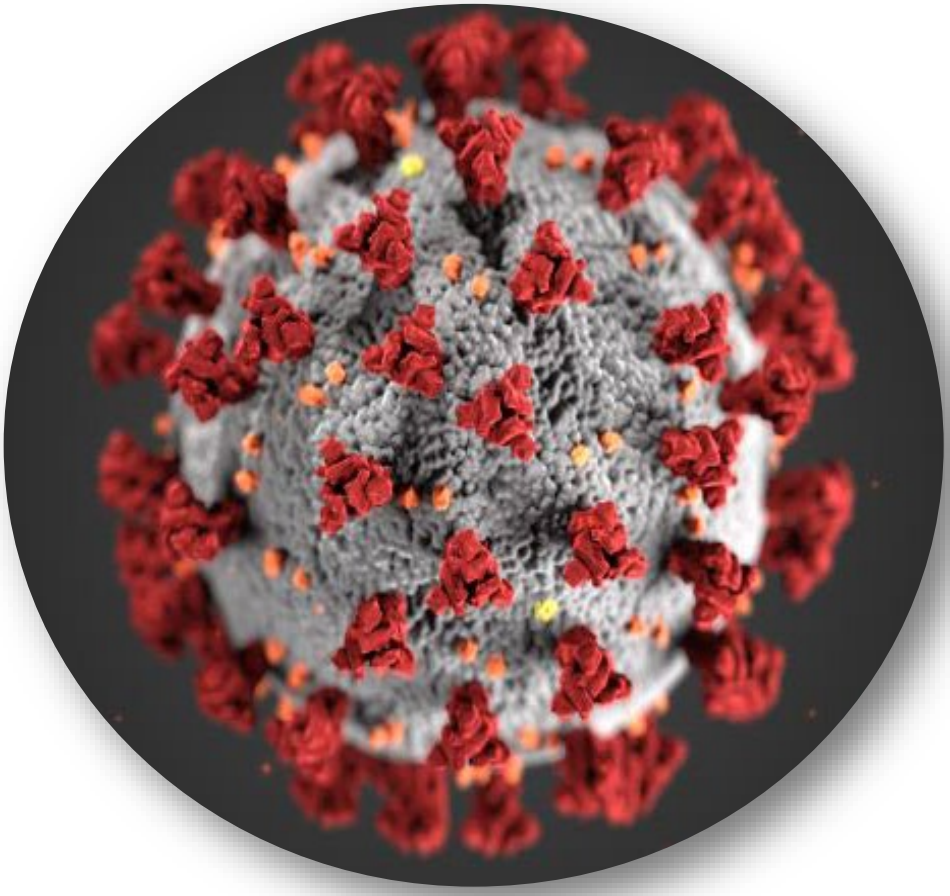
- Upgraded the Select Agent (bioterrorism) HL7 message system for reporting data to CDC. The Select Agent Program for biological threats completed an extensive upgrade to the HL7 message system handling data reporting to CDC. Michigan was the first lab in the United States to receive a 100% pass rate with the formal LRN-B version 3 test message suite on the first attempt.



Division of Infectious Disease - Microbiology and Virology Sections

- DID added three new regional laboratories for a total of seven.
- Enteric bacteriology and PulseNet scientists received a Food and Drug Administration (FDA) Group Recognition Award for their substantial contribution to the Pig Ear Salmonellosis Outbreak Investigation.
- DID established a new Bioinformatic section for the computational analysis of genetic sequencing to assist state and local communities by providing rapid outbreak and surveillance data for emerging and evolving disease threats.
- Created multiple “how-to” presentations for COVID-19 specimen collection and shipment to BOL.
- Collaboration among reference bacteriology, Pulse Net scientists and bioinformatics supported the investigation of a New Delhi metallo-beta-lactamase cluster at a long-term care facility in Michigan.
- Pulse Net scientists substantially contributed to a statewide outbreak investigation of Salmonellosis associated with red onions, peaches, and melons.
- BOL Tuberculosis (TB) unit supported clinical laboratory partners with TB testing throughout the ongoing COVID-19 pandemic.
- As part of ongoing investigations, PulseNet and TB genotyping teams have sequenced more than 5,000 specimens for COVID 19.
- DID managers presented at 13 virtual conference meetings, moderated one virtual conference, served as a week-long guest lecturer for a Legionella course, and gave two guest-lectures at the University of Michigan in January.
- APHL selected the BOL TB Unit Manager and senior scientist to contribute their expertise for implementation of MALDI TOF for Mycobacterium Tuberculosis Complex Identification in state public health laboratories across the United States.

- FDA awarded a food safety grant to the Microbiology section (up to $2.3 million over five years) to enhance the capacity and capabilities in the detection of bacterial pathogens in food products and improve the laboratory capacity for food defense assignments and outbreak responses in the State of Michigan.
- DID conducted FERN Triage and bioterrorism surge exercises.
- The Virology section was selected as a National Hepatitis C Virus Reference Center for the United States.
- DID successfully developed First Responder testing for COVID-19.
- DID verified nasal self-collection technique for COVID-19 and created an instruction document.



Division of Chemistry and Toxicology - Newborn Screening Section and Analytical Sections

- Implemented screening for Spinal Muscular Atrophy (SMA).
- Awarded a CDC Grant ($314,370) for *"Enhancing Disease Detection in Newborns: Building Capacity in Public Health Labs".*
- Two major newborn screening Laboratory Information Management Systems (LIMS) upgrades were implemented – server migration and LIMS software enhancements.
- Purchased and validated a new tandem mass spectrometer instrument, QSight, for X-linked Adrenoleukodystrophy (XALD) 2nd tier testing.
- Added Lysosomal Storage Disorders (LSD) to Saturday testing.
- The Analytical Chemistry (AC) section developed a multi-analyte method for metals in urine and whole blood by inductively coupled plasma tandem mass spectrometry.
- Developed method for arsenic speciation in urine by liquid chromatography inductively coupled plasma tandem mass spectrometry and mercury speciation in whole blood by gas chromatography inductively coupled plasma tandem mass spectrometry.
- Forty-three spices, teas, and supplemental samples were analyzed for a panel of metals.
- One-hundred eighty Food Emergency Response Network (FERN) surveillance samples were analyzed for a panel of metals and organic compounds.
- Developed method for PFAS in serum and continue to develop methods for analysis of PFAS compounds in agriculture products, including home grown products.
- Validated new method for sulfur mustard metabolite SBMSE in urine and serum

using ultra high-performance liquid chromatography tandem mass spectrometry.

- Characterized new lots of material for cyanide, nitrogen mustard and organophosphorus nerve agent in serum and/or urine.

BUREAU OF LABORATORIES ROLE IN EMERGENCY MEDICAL COORDINATION

The Bureau of Laboratories (BOL) follows the National Incident Management System (NIMS) guidelines, a standardized system for emergency management and incident response activities utilizing the Incident Command System (ICS) as a common structure enabling organizations and agencies to work together in a predictable and coordinated manner. NIMS and ICS course training are required for all public and private agencies who receive federal preparedness funds.

How does this all come into practice during an incident for the BOL?

Public Act 390 provides support for planning, mitigation, response, and recovery; also, the creation of the Michigan Emergency Management Advisory Council. The Michigan Emergency Management Act prescribes the powers and duties of state and local agencies and officials.

The State Emergency Operations Center (SEOC) is where state, local, and federal agencies coordinate the response to a disaster, emergency, or act of terrorism. The Governor, State Director of Emergency Management, and Homeland Security are the lead entities providing direction of all state resources at the SEOC when responding to and recovering from an incident. Under the direction of the Governor, the SEOC coordinates planning and response activities to support Michigan governmental actions. The SEOC also serves as the liaison to local, nonprofit, private resources, interstate, and the Federal Emergency Management Agency (FEMA).

The Michigan Emergency Operations Base Plan defines activities for MDHHS as the lead state agency for human and health service, including the Public Health Code, PA 368, and amendments. Emergency preparedness is the ability to respond to all types of public health incidents and to build resilient communities. The Bureau of Emergency, Trauma, and Preparedness (BETP) is the direct link to the emergency managers in the SEOC when the SEOC is activated.

MDHHS BETP maintains responsibility to coordinate the activities of the Community Health Emergency Coordination Center (CHECC). The CHECC can be activated in two ways: Michigan State Police - SEOC Activation for an emergency that has human health consequences or MDHHS activation by the department director along with a request for a public health

emergency even if the incident has not yet been declared as an emergency or disaster. The CHECC utilizes NIMS and ICS, supports the SEOC, and coordinates with the Regional Medical Coordination Centers (RMCCs) & other partner agencies. The CHECC is a centralized operation that coordinates the MDHHS response overall, provides information to the MDHHS Executive Group, provides technical assistance and consultation, coordinates federal support and assistance, and disseminates public health and healthcare information.

The BOL has a role in the CHECC when the human health emergency requires laboratory testing or when the CHECC needs additional support staff for large scale incidents. The laboratory is aligned under the Operations Section, Public Health Branch. BOL representatives report to the Operation Section Chief following the ICS organizational structure. The CHECC Laboratory Operations staff works with the BOL Liaison to provide and disseminate pertinent laboratory information. The liaison relays BOL information to the CHECC Laboratory Operations staff for the information to move up the organizational chain.

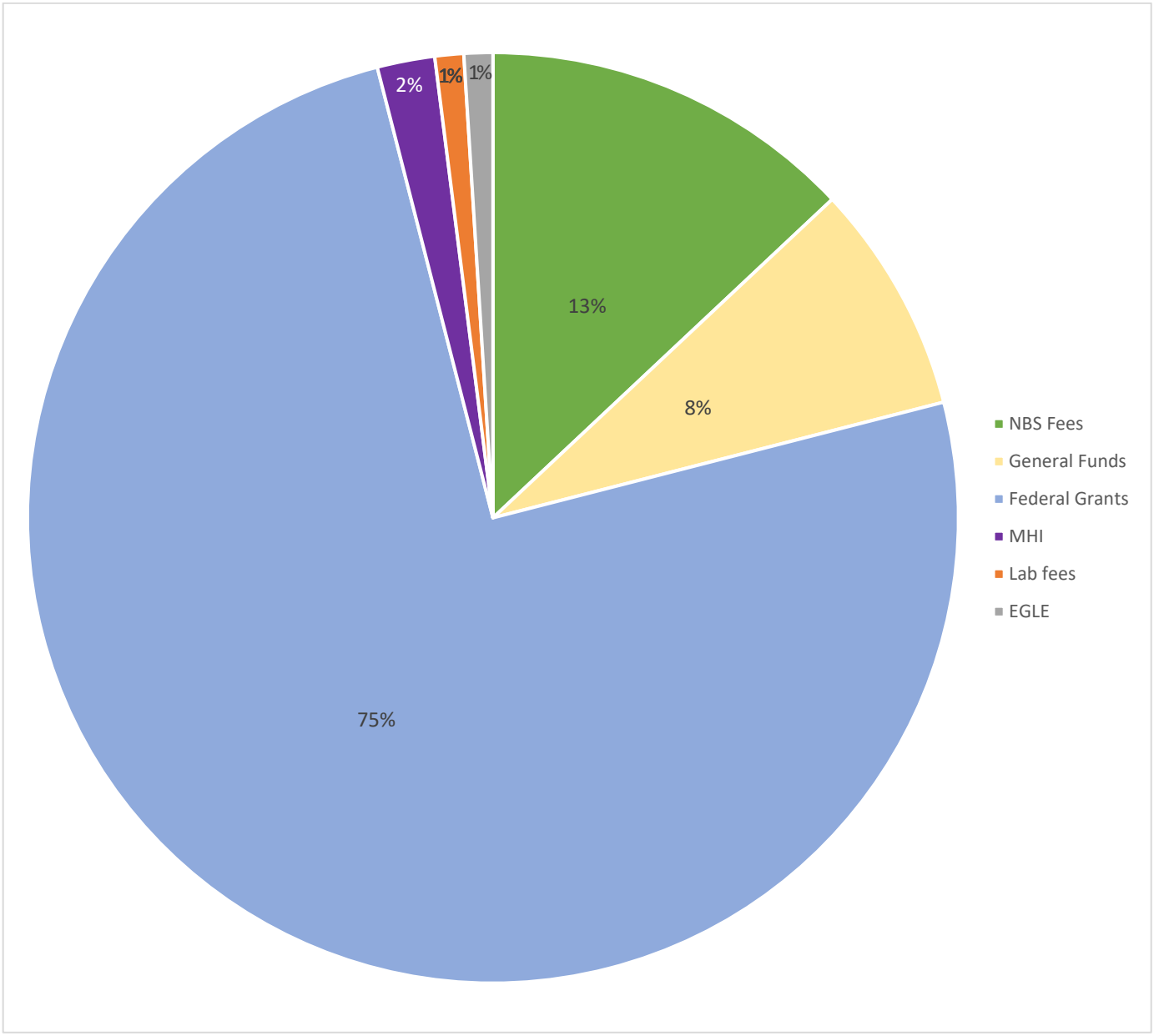
The BOL has dedicated employees that act in the CHECC Laboratory Operations position and BOL Liaison position. These employees have successfully completed CHECC training, NIMS and ICS training, WEB EOC training, and MIHAN training. This additional training provides the employee with the necessary educational background to understand the basic operational components of the CHECC.

Source: LabLink Summer 2020, Volume 25, Number 3

FY2020 – BY THE NUMBERS

MDHHS Bureau of Laboratories	**6.8 million tests** For State of Michigan Residents	
Infectious Disease	**195,812** specimens **434,738** tests	**112,000** individuals
Newborn Screening	**6,376,216** tests	**113,861** Newborns
Blood Lead & Environmental Lead	**13,410** tests for blood lead & environmental lead	**8,400** individuals & households
Chemistry & Toxicology Division Fish Testing	**600** fish tested for PCB & chlorinated pesticides **>1,100** fish tested for heavy metals	All Michigan Residents Eat Safe Fish Guide
Per & Polyfluoroalkyl Substances	**2,140** serum & water samples **1,000** fish **112** deer	All Michigan Residents

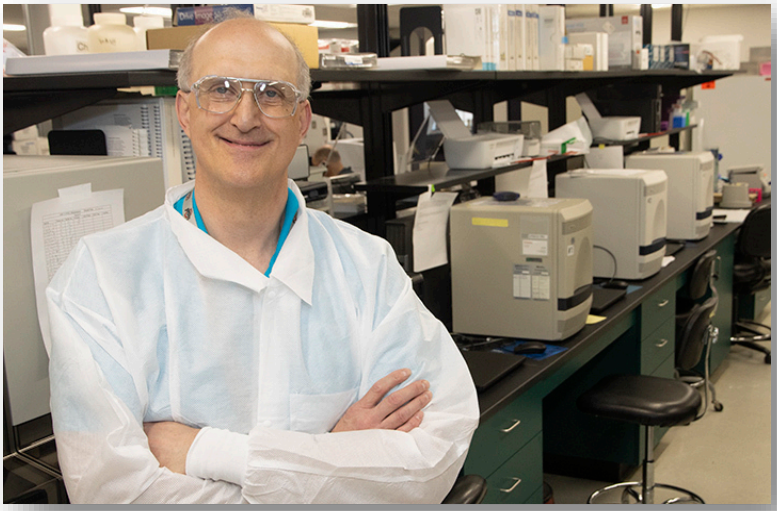
FY 2020 FUNDING SOURCES



BOL RAMPS UP TO MEET INCREDIBLE COVID-19 TESTING CHALLENGE

In March of 2020, a deadly new virus, COVID-19 began to appear in Michigan, and, within weeks, the Detroit area became an epicenter of the disease nationwide.

Kevin Rodeman, a senior microbiologist in the Virology and Immunology Section at the Michigan Department of Health and Human Services (MDHHS) State Laboratory in Lansing, and his fellow scientists have been at the heart of the state's efforts to test for new outbreaks of COVID-19 and try to limit the spread of the virus statewide.



It's proven to be an incredible challenge for the 20-member team as they saw demand for testing specimens increase 40-fold, peaking at about 1,200 tests each day and faced the necessity of acquiring new equipment to handle higher testing volumes.

The Bureau of Laboratories has been integral in building the state's testing infrastructure, which is critical to understanding and slowing the spread of disease.

This testing infrastructure includes a network of private laboratories and major hospitals that have worked with the bureau to prepare themselves for this testing. In the early weeks of COVID-19 in Michigan, the state's virology section did all the testing for the state, but since then, these private labs and hospitals have stepped in to also provide testing.

Having a partnership of the state and regional public health laboratories, private clinical laboratories and hospital clinical laboratories has allowed Michigan to achieve the goal of testing a minimum of 15,000 specimens for COVID-19 daily.

Many bureaus of the Public Health Administration have been critical to the state's efforts and success in fighting the COVID-19 crisis and have been working around-the-clock since January 2020. Along with the BOL, the Bureau of Health and Wellness has led coordination with local health departments, the Bureau of EMS, Trauma and Preparedness has coordinated the state's emergency preparedness efforts, and the Bureau of Epidemiology and Population Health has led the state in analysis and sharing of data and informing policies.

Original Source: HOPE Weekly, July 21,2020

TRAINING AND TOURS

Laboratory Tours:

- Thirty hours in laboratory tours and visitor meet and greets. Laboratory tours were suspended in March 2020 due to the COVID-19 pandemic.

K-12 Outreach:

- Two career fairs reaching approximately 2,100 students.
- Ten science demonstrations with approximately 2,500 students participating.
- Thirteen college student interns volunteered to assist with K-12 outreach.
- Seventeen videos of science experiments were produced by the K-12 science education program to share with schools and libraries during the COVID-19 pandemic.

Biological Threat (BT) Packaging & Shipping Training:

- Twenty-one classes held at 8 facilities throughout the State of Michigan along with thirteen virtual classes.
- Total of 251 participants certified in BT packaging and shipping.

Chemical Threat (CT) Training:

- Ten classes held throughout the State of Michigan with 128 participants from local hospitals and Public Health Departments attending.
- Two CDC, Laboratory Response Network-Chemical, Specimen Packaging and Shipping Exercise successfully completed; 16 consecutive years passed with 100% rating.

COVID-19 training:

- Created the training program for the Abbott BinaxNOW antigen test.
- Ten trainings were given to statewide partners and the Michigan National Guard.
- Four local health departments and one hospital received training along with over 100 Michigan National Guard members who in turn have trained approximately fifty additional locations.
- Two-hundred people received other training opportunities held via Microsoft TEAMS.
- Two biosafety videos produced and published to YouTube for COVID-19 Point of Care instrumentation with 17,000 views to date.

PUBLICATIONS

Shigella sonnei Outbreak Investigation in the Setting of a Municipal Water Crisis – Genesee and Saginaw Counties, Michigan, 2016. McClung, Karwowski, Castillo, McFadden, Collier, Collins, **Soehnlen, Dietrich**, Trees, Wilt, Harrington, Miller, Adam, Rese, Cope, Fullerton, Hill, and Yoder. 2019 AJPH, June 2020.

Protracted, Intermittent Outbreak of *Salmonella* Mbandaka Linked to a Restaurant Michigan, 2008–2019, MMWR. 2020.

Cluster of Human *Salmonella* Guinea Infections: Reported Reptile Exposures and Associated Opportunities for Infection Prevention — Ohio, 2019–2020. MMWR. 2020.

GP42 Collection of Capillary Blood Specimens-7th Edition, **Miller,** and others, CLSI, 2020.

Laboratory Response Network-Chemical (LRN-C) Level 3 Resource Handbook, APHL, **Miller,** and others, 2020.

PRESENTATIONS

2020 APHL National Meeting Oral Presentation: Michigan's Experience with Implementing SMA by multiplexing with the established SCID assay.

2020 APHL National Meeting Oral Presentation: Homocystinuria Screening: Michigan's Experience.

2020 APHL National meeting: Two posters presented by APHL Antimicrobial resistance fellow (TB track) and Bioinformatician.

1. Increased prevalence of bovis BCG isolates from Sterile sites – A 2010 -2019 Michigan study.
2. Disseminated Neisseria gonorrhea outbreak within Michigan 2019.

WHOLE GENOME SEQUENCING OF SARS CoV-2

Since the first case of SARS-CoV-2 was detected at MDHHS Bureau of Laboratories (BOL) in mid-March, three laboratory sections (Microbiology, Virology, and Bioinformatics) have worked together as part of a sequencing group to bring high throughput sequencing protocols online, analyze the data, and provide support to our epidemiology partners in response to the pandemic. In the past nine months, the group has been able to sequence 5,070 SARS-CoV-2 samples that were either tested by BOL or submitted by clinical partners around the state for surveillance.

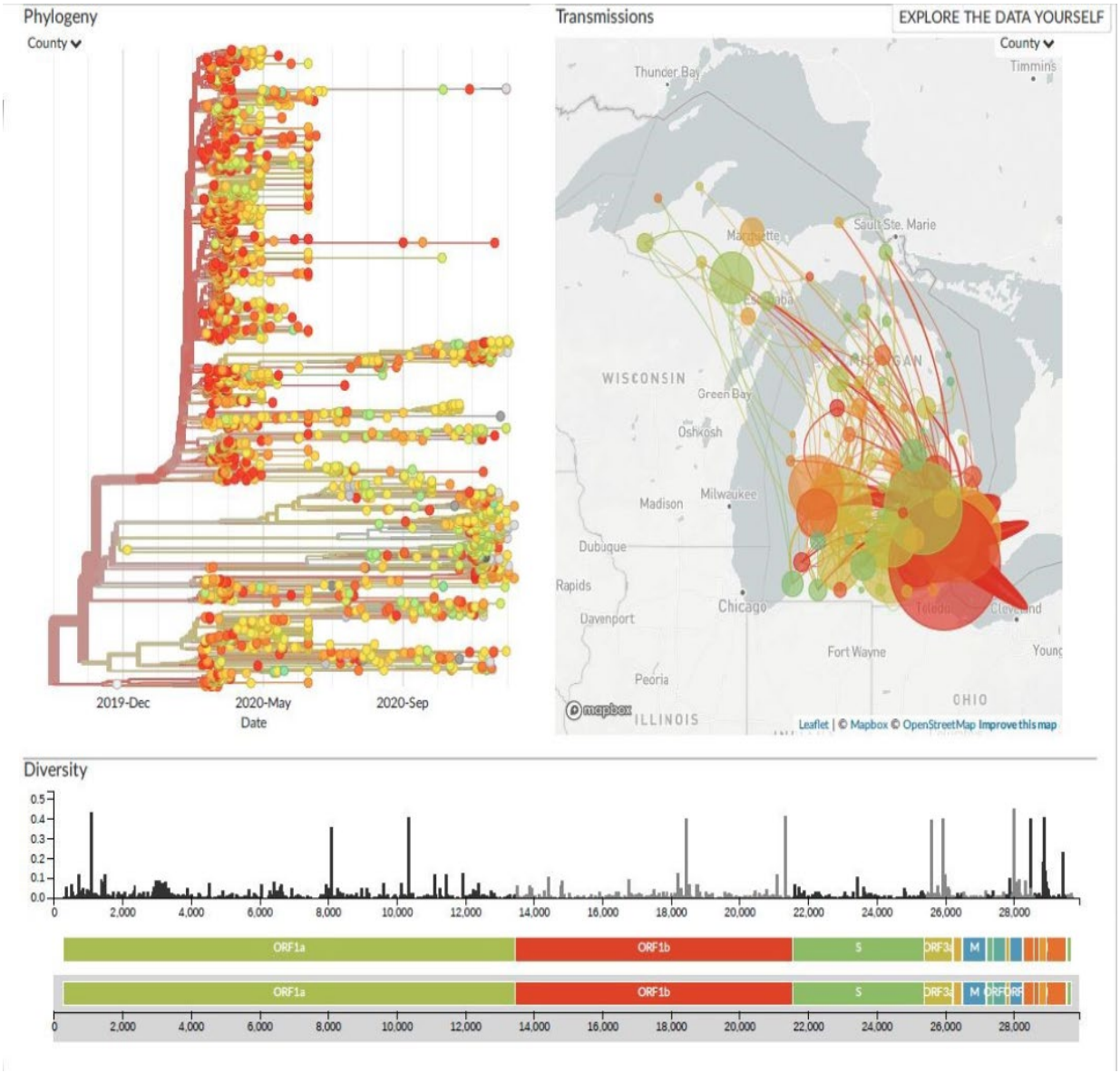
SARS-CoV-2 is an RNA virus that belongs to the coronavirus family; it also includes other notable viruses such as SARS, MERS, and the common cold. The genome for SARS-CoV-2 is small at 29,900 nucleotides in length and only 11 genes. While the mutation rate for RNA viruses tends to be very high, SARS-CoV-2 only generates two mutations per month on average, which is half the rate of influenza and a quarter the rate of HIV. However, not every mutation will provide an advantage to the virus and most mutations will go undetected since they result in either no changes or a non-viable virus. These mutations allow us to generate a picture of how viruses from different people or regions may be related, how the virus is moving, where it came from, or how it is changing. For instance, through whole genome sequencing, researchers were able to identify that the closest related coronaviruses to SARS-CoV-2 were found in bats and pangolins.

Within Michigan, whole genome sequencing of SARS-CoV-2 has helped us to understand the virus and provide support to the pandemic response. By examining the virus at the genomic level along with the date of infections, we can generate broad transmission dynamics to watch how the virus might be moving around the state or across state borders.

On a smaller scale, we can examine and provide support to epidemiologists as they investigate cluster outbreaks within different facilities by examining slight differences in the genome. While examining the SARS-CoV-2 genomes, we also monitor and track variants that may be of important clinical or diagnostic importance.

Specifically, variants that may result in more severe clinical outcomes or affect our ability to accurately identify a positive specimen. As we continue to respond to the SARS-CoV-2

pandemic, whole genome sequencing will help to provide insight on changes that we see within the virus and how that might affect the response.



Transmission dynamics and genomic differences that can be observed in Michigan through whole genome sequencing analysis of SARS-CoV-2

Courtesy of MDHHS BOL

Source: LabLink. Winter 2021, Volume 27, Number 1

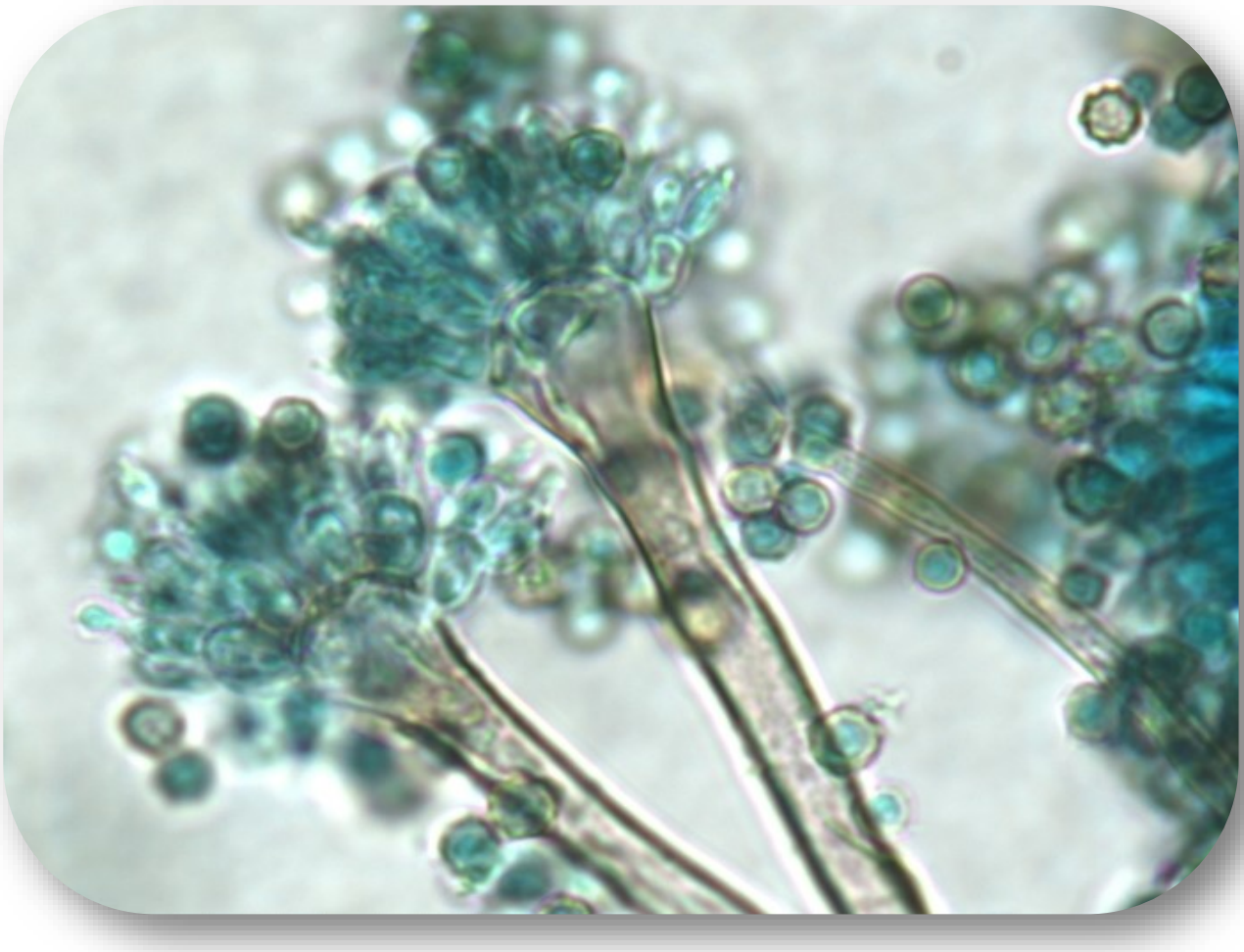
2020 PROTOCOLS VALIDATED

33 test validations and verifications performed

Title
Tandem Mass Spectrometry for the Detection of ADA, SCID, XALD and GAMT Disorders using the NeoBase2 kit
Quantitation of Lysophosphatidylcholines in Dried Blood Spots by Liquid Chromatography-Tandem Mass Spectrometry
Mercury Determination in Human Urine for CDC's Chemical Terrorism Emergency Response Program
Utility of Multiheaded Adapter Vortexing for Bacterial DNA Extraction Prior to 16S rDNA Sequencing
Combination Products Matrix Extension Using FSIS FERN GC-MS Screening of Food Matrices Tox1 Method
HCV Viral Load (Quantitative) Using the COBRAS AmpliPrep/COBRAS TaqMan 48 Analyzer with the COBRAS HCV Test Kit v 2.0
Validation of Aptima Combo Kit on Urine Specimens Collected from Age Group 13
Testing *Mycobacterium tuberculosis* Complex Isolates for Susceptibility to Levofloxacin
Multiplexed Real Time PCR Screening Method for Spinal Muscular Atrophy and Severe Combined Immunodeficiency Syndrome
CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel for Emergency Use Authorization Only
Instrument Verification for Qiagen EZ1
Agilent 5110 ICP-OES Method Extension Verification Study
Multiplex Real-time PCR for the Detection of OXA-23-like, OXA-24/40-like, and OXA-58-like Genes
Verification of the CEPHEID GeneXpert system for the Detection of Nucleic Acid from the SARS-CoV-2 Virus

E-Swab Verification for the Collection of Human Clinical Respiratory Specimens Tested for COVID-19
Saline Verification for Use as Collection Media for COVID-19 Testing AND Saline Swab Stability Verification for the Use as a Collection Media for COVID-19 Testing
Human Epithelial Cells Type 2 (Hep-2) Validation for Use as Human Serum Control Material for COVID RT-PCR testing
Verification of ABI 7500 SN 275030194 for the Use of the EUA RT-PCR Detection of COVID-19 Virus in Human Clinical Respiratory Specimens
ThermoFisher Scientific TaqPath COVID-19 Combo Kit Using the Kingfisher for Emergency Use Authorization Only
Validation of Yeast Identification Using the MALDI-TOF Instrument
Verification of the Zeus ELISA Borrelia burgdorferi VlsE1/pepC10 IgG/IgM Test System
Comparison of Automated BIOMIC V3 Versus Manual AST Readings
EUA Validation of Aptima SARS-CoV-2 Assay (Panther System)
A Quantitative Method for the Targeted Analysis of Fentanyl, Fentanyl Analogs, Utopioids, and Related Metabolites in Human Scrum via Automated 96-Well Plate Stable Isotope Dilution - Solid Phase Extraction - Liquid Chromatography - Tandem Mass Spectrometry
Validation of Jamestown Canyon IgM Capture Antibody Assay
Perkin Elmer VICTOR NIVO Instrument Verification
Instrument Verification for BioFire Film Array 2.0 COVID-19 Test
Validation of the Platelia SARS-CoV-2 Total Antibody Assay on the EVOLIS
Validation of the SARS-CoV-2 Total Antibody Assay on the ADVIA Centaur XPT
Analysis of Serum for Perfluoroalkyl Substances by Automated 96-well Solid Phase Extraction High Performance Liquid Chromatography Tandem Mass Spectrometry

Quantitation of Lysophosphatidylcholine in Dried Blood Spots by Liquid Chromatographic QSight Mass Spectrometry
Analysis of Sulfur Mustard Metabolite SBMSE in Urine and Serum by Automated 96-Well Solid Phase Extraction Ultra High-Performance Liquid Chromatography Tandem Mass Spectrometry
Addition of Moxifloxacin to the AP Secondary Drug Susceptibility Panel for Mycobacterium tuberculosis complex



SPINAL MUSCULAR ATROPHY ADDED TO THE NEWBORN SCREENING PANEL

Newborn Screening is a public health program required by Michigan law to find babies with rare but serious disorders that require early treatment. All babies need to be tested to find the small number who look healthy but have a rare medical condition. Each year more than 250 Michigan babies are found to have a disorder detected by newborn bloodspot screening. As of March 2020, the Newborn Screening Program added Spinal Muscular Atrophy (SMA) to the screening panel.

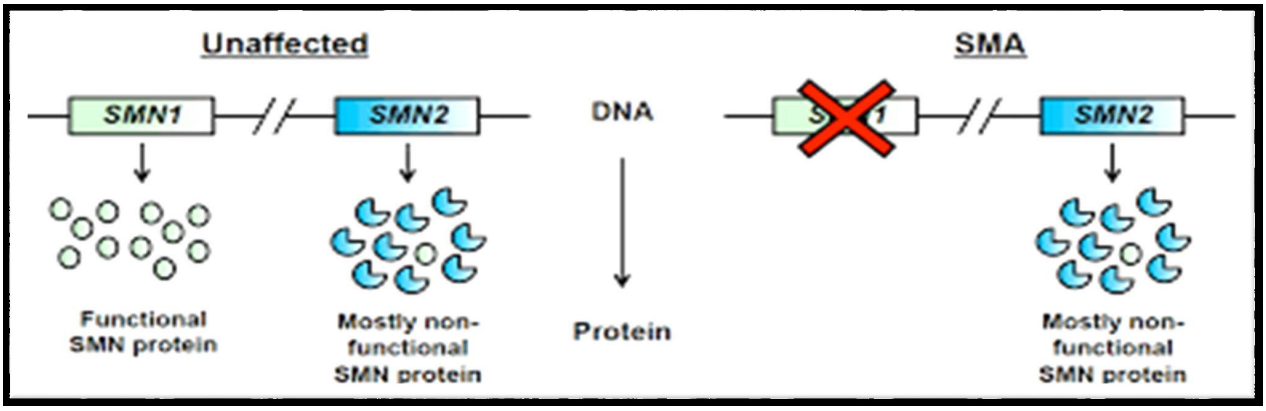
SMA is characterized by muscle weakness and atrophy of the skeletal muscles through the deterioration of motor neurons that control muscle movement. A child will be noticeably weak and delayed in developmental milestones. Symptoms also include trouble breathing, coughing, and swallowing. There are five types of SMA with symptoms ranging from moderate to severe.

Treatment should occur as soon as possible, prior to patients becoming symptomatic to prevent non-repairable motor neuron loss. Without treatment, the life expectancy of the most common type of SMA is 2 years of age. There are three FDA approved drugs available for treatment.

	FDA Approved Drug Therapies		
	Spinraza	**Zolgensma**	**Evrysdi**
Age to take	Anytime	< 2 years old	> 2 months old
Dosing	Every 4 Months	Once	Daily
Administration	Intrathecal Injection (IT)	Intravenous Infusion (IV)	Oral
Duration	Lifetime	Once	Lifetime

SMA is caused by mutations in the survival motor neuron (SMN) gene. There are two highly homologous copies that have only five base-pair differences, SMN1 and SMN2. SMN1 produces full-length transcriptional mRNA, and SMN2 produces a small amount of full-length mRNA and due to splicing differences, primarily produces an attenuated mRNA transcription that lacks exon 7 of the gene. Ninety-five percent of SMA individuals are homozygous for the deletion of the exon

7 in the SMN1 gene. The severity of the disease correlates to SMN2 copy number and the amount of functional protein present. Treatment options focus on correcting splicing errors on RNA produced from SMN2 gene (Spinraza), gene therapy to replace/repair the SMN1 gene



(Zolgensma) and increasing functional SMN protein through the SMN2 gene (Evrysdi).

SMA screening method detection finds the absence of the SMN1 exon 7 deletion by Real-Time PCR (RT-PCR). The SMN1 target was multiplexed with the already established RT-PCR assay detection Severe Combined Immunodeficiencies (SCID) with RNaseP as a reference gene to ensure satisfactory specimens. The SMN2 copy number is not determined in the newborn screening laboratory.

Duration (11/4/2019 to 9/22/2020)	
Total Babies Screened (initials)	92,434
Total SMA Positive Screens	10 patients (12 specimens)
False Positive Rate	0% to date
False Negative Rate	0% to date
Positive Predictive Value* (PPV)	100% to date

Michigan has screened over 92,000 babies in the past 10 months and has identified 10 patients with SMA. All 10 patients were confirmed to have Spinal Muscular Atrophy. Michigan's incidence rate of SMA detection is 1 in 9,243 to date.

References:

Prior TW, Snyder PJ, Rink BD, Pearl DK, Pyatt RE, Mihal DC, Conlan T, Schmalz B, Montgomery L, Ziegler K, Noonan C, Hashimoto S, Garner S. 2010. Newborn and carrier screening for spinal muscular atrophy. Am J Med Genet Part A 152A:1608–1616.

Pyatt RE, Prior TW. 2006. A feasibility study for the newborn screening of spinal muscular atrophy. Genet Med 2006:8(7):428–437.

CureSMA.org

Source: LabLink Fall 2020, Volume 26, Number 4

SAFETY

The Bureau of Laboratories is actively committed to preserving the health and safety of its laboratory staff and to protecting the community and the environment. Below are the 2020 safety statistics and activities.

Laboratory Building Upgrades

- New passive capture fume hood in TB unit installed January 2020
- Remodel of Chemistry Offices and Safety Office
- Roof of building repaired
- Siding removed on building and leaking windows were sealed
- Room 100 was expanded in size
- DASH area remodeled

Laboratory Safety Actions

- One noise complaint Investigation
- One biosafety accident investigation
- One MIOSHA recordable Injury
- Onsite influenza immunization, rabies titer draws and TB skin test clinics
- Five Laboratory Safety Committee meetings
- COVID Safety Plan developed
- COVID Exposure Control Plan developed
- Formaldehyde and Xylene monitoring plan developed

Safety Training

- Forty staff received initial safety orientation
- One individual received additional safety training due to job transfer

- Thirty-seven individuals attended DTMB Infrastructure Active Shooter Training
- Sixteen individuals had Hazardous Chemical Waste Transportation and Storage training
- One hundred eighteen individuals received Annual Bloodborne Pathogens and Chemical Safety Refresher Training
- Thirty-seven individuals trained in agent specific biosafety, biosecurity, incident response and insider threat for the select agent program
- Four individuals attended HAZWOPER eight-hour refresher training
- Eighty-one individuals received N-95 fit tests (multiple brands and sizes)
- Fifty-nine staff received CAPR respirator training

DR. MARTY K. SOEHNLEN, NATIONAL AWARD HONOREE

Dr. Marty K. Soehnlen PhD, MPH, PHLD(ABB), Infectious Disease Division Director for the Bureau of Laboratories (BOL) was an award honoree. Dr. Soehnlen received the Emerging Leader Award which honors a laboratorian whose leadership has been instrumental in one or more advances in laboratory science, practice, management, policy, or education within five to ten years of working at a publicly funded laboratory that conducts testing of public health significance. This recipient must also be employed by an APHL member institutional laboratory. Dr. Soehnlen was nominated by three peer public health laboratories located across the United States and was voted to receive this award by an APHL Awards Vetting Committee.

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